REMARKS

Election

Applicants hereby elect *group I* containing claims 1-65, *with traverse*, as set forth below.

As regards the species restriction, applicants elect as follows:

For the vasoconstrictor: phenylephrine.

For the penetration enhancer: lecithin.

For the therapeutic agent: ketoprofen.

The *elected product claims* specifically or generically encompassing the elected species *phenylephrine* are: 1, 2, 3, 4, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 59, 60, 61, 63, 64, 65.

The *elected product claims* specifically or generically encompassing the elected species *lecithin* are: 1, 9, 10, 11, 12, 17, 18, 19, 20, 21, 22, 23, 59, 60, 61, 63, 64.

The *elected product claims* specifically or generically encompassing the elected species *ketoprofen* are: 1, 22, 23, 29, 30, 31, 32, 39, 40, 43, 44, 45, 46, 47, 48, 59, 60, 61, 63, 64, 65.

For examiner's convenience in the event the requested withdrawal is granted based on applicants' traverse, applicants also identify below, the various elected species claims in non-elected group II:

The *non-elected method* claims specifically or generically encompassing the elected species *phenylephrine* are: 66, 67, 68, 69, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 124, 125, 126, 128, 129, 130, 131, 132, 133, 134, 135, 148, 150.

The *non-elected method claims* specifically or generically encompassing the elected species *lecithin* are: 66, 74, 75, 76, 77, 82, 83, 84, 85, 86, 87, 88, 124, 125, 128, 129, 131, 133, 134, 135, 148, 150.

The *non-elected method claims* specifically or generically encompassing the elected species *ketoprofen* are: 66, 87, 88, 94, 95, 96, 97, 104, 105, 108, 109, 110, 111, 112, 113, 124, 125, 126, 128, 129, 130, 131, 134, 135, 138, 139, 142, 143, 148, 150.

Traversal

Applicants *hereby traverse* the restriction under MPEP 806.05(h) between a Product and Process of Using. Applicants further contest and object to the summary redaction of the earlier allowance of claims 66-150 with examiner not relying upon any prior art support.

This section of the MPEP states, in full:

> "A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another

materially different product; or (B) the product as claimed can be used in a materially different process.

The burden is on the examiner to provide an example, but the example need not be documented.

If the applicant either proves or provides a convincing argument that the alternative use suggested by the examiner cannot be accomplished, the burden is on the examiner to support a viable alternative use or withdraw the requirement."

Examiner has stated: "*In the instant case*, the process for using the product as claimed can be practiced with another materially different product. For example, the specification (p.1) points out that Lidoderm is useful for the treatment of chronic pain."

The MPEP makes clear that a restriction must be based on the "process of using *as claimed*." Applicants' independent method (process of using) claim 66, which is original to the filing of the application, reads as follows, with emphasis added:

"A method of *topically delivering and localizing* therapeutic agents, comprising the steps of:

using a vasoconstrictor for *retarding vascular dispersion* of a therapeutic agent; in combination with

using a penetration enhancer for *facilitating*

penetration of said vasoconstrictor and said therapeutic agent through a patient's skin."

As claimed, applicants' method recites "delivering and localizing therapeutic agents." It further recites "retarding vascular dispersion" using a vasoconstrictor. It further recites "facilitating penetration" of both "said vasoconstrictor and said therapeutic agent" using a penetration enhancer.

Page 1 of applicants' specification, as referenced by examiner, states: "it appears that the only topical prescription analgesic specifically marketed for chronic pain is the LIDODERM® Patch." Lidoderm® is recited in applicants' disclosure *as an example of a limitation in the prior art which is overcome by applicants' invention*, and as such it certainly cannot be used to practice applicants' invention because applicant's invention is specifically designed to overcome limitations of prior art products such as Lidoderm® and its method of use.

Specifically, the Lidoderm patch is described at the web page http://www.rxlist.com/lidoderm-drug.htm, as follows:

> "Each adhesive patch contains 700 mg of lidocaine (50 mg per gram adhesive) in an aqueous base. It also contains the following *inactive ingredients*: dihydroxyaluminum aminoacetate, disodium edetate, gelatin, glycerin, kaolin, methylparaben, polyacrylic acid, polyvinyl alcohol, propylene glycol, propylparaben, sodium carboxymethylcellulose, sodium

polyacrylate, D-sorbitol, tartaric acid, and urea"

Based on the foregoing, examiner is in error is stating that applicants' method can be practiced with Lidoderm®. It cannot. In making this statement, it is clear that examiner has not properly considered applicant's method, *as claimed*.

Applicants' method *as claimed* is not only to transdermally apply a therapeutic agent, but to do so in a way, *as claimed*, which is both "facilitating penetration" and "retarding vascular dispersion" of the therapeutic agent. This is central to applicants' invention, and Lidoderm® does not implement one or both of these critical aspects of applicants' method *as claimed*. Lidoderm® contains lidocaine, as well as a number of other "inactive ingredients." Lidoderm® does not appear to contain any "penetration enhancer for facilitating penetration" as claimed by applicant. Further, Lidoderm® clearly does not contain any "vasoconstrictor for retarding vascular dispersion" as claimed by applicant. Consequently, it is not possible to use Lidoderm® to practice applicants' method as claimed.

Lidoderm® does not "facilitate[e] penetration" using a penetration enhancer as claimed by applicants. Further, Lidoderm® does not "retard . . . vascular dispersion" using a vasoconstrictor as claimed by applicants. These are central to applicant's method as claimed, and applicant's method "as claimed" simply cannot "be practiced with Lidoderm®," which is

the example provided by examiner, because Lidoderm® lacks one or both of these claimed recitations of applicants' method. As such, this portion of the restriction is hereby traversed.

Under MPEP 806.05(h), the "burden is [now] on the examiner to support a viable alternative use or withdraw the requirement." Applicants respectfully request withdrawal of this restriction.

Additionally, applicants hereby traverse statements (a) through (e) recited at the end of the MPEP 806.05(h) restriction. The essence of applicant's invention is to effectively deliver and localize therapeutic agents. Group I and group II are tightly interrelated when the invention, as claimed, is properly understood in this way. Applicants' invention is based not on the therapeutic agent that is delivered, per se, but on a product which facilitates effective delivery and localization of therapeutic agents and a method in which delivery and localization effectively occurs. Applicants' invention is at once a product for effective delivery and localization and a method of using the product to effectively deliver and localize. These (a) do not appear to have separate status in the art (b) do not involve divergent subject matter (c) are unlikely to require fields of search which are substantially different (d) are unlikely to raise prior art applicable to the product but not the process or vice versa and

(e) are unlikely to raise different 101 or 112 issues. All of these statements by examiner rest on a complete misreading of applicants' invention.

Traversal and Objection to the Redaction of Allowed and Allowable Claims

Finally, applicant traverses both the group and the species restrictions as being improper based on the earlier office action which allowed claims 66-150, and which indicated that claims 9-12, 17-21, and 23-65 would be allowed if rewritten as independent claims. Examiner here says "all of examiner Kennedy's conclusions are redacted herein because . . . US 7,273,887 . . . is more analogous." Yet, examiner also says "*the '887 patent was not relied for said conclusions . . .*"

Not only has examiner withdrawn an earlier allowance of claims 9-12, 17-21, 23-65, and 66-150 *without relying on any prior art* under 35 U.S.C. § 102 or 103, but examiner has also then restricted these claims, simply making unsupported reference to US 7,273,887, which reference, in fact, would not justify this redaction of the earlier allowance. This raises issues of due process, because the redaction of an earlier allowance must be made on the merits. Simply stating that the '887 patent is "more analogous" and then having it be "not relied" upon is woefully insufficient. Examiner has provided no

authority for being able to redact an allowance without relying on prior art, and for then restricting these allowed claims from examination thus denying applicants the right to argue against this redaction.

Under 35 U.S.C. § 102, applicants are "entitled to a patent unless" examiner presents a prior art basis to deny the patent. Claims 9-12, 17-21, 23-65, and 66-150 stand allowed. If examiner believes the allowance needs to be redacted, he should support this redaction in a substantive office action on the merits. He should not simply provide a patent number, state that it was "not relied" upon, redact the allowance nonetheless, and then compound this improper redaction by issuing a restriction affecting already allowed claims *which effectively denies applicants an opportunity under due process of law to contest the redaction on the merits.*

For these reasons as well, applicants respectfully request withdrawal of the restriction, *and further request reinstatement of the allowance of claims 9-12, 17-21, 23-65 and 66-150 unless and until a redaction on the merits is properly presented and can be sustained*, which redaction applicants believe is not justified based on the cited prior art.

Information Disclosure

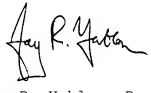
Also enclosed herewith is an information disclosure

for pre-grant publication US 2004/0076648. This publication which applicant has not yet reviewed for substantive content, was just cited in a restriction on June 1, 2009 in applicants' counterpart case US 11/569,805, received today.

Conclusion

Based on the foregoing amendment and remarks, applicants respectfully requests withdrawal of the restriction as between groups I and II, and reinstatement of the allowance of claims 9-12, 17-21, 23-65 and 66-150. For examiner's convenience in the event of a restriction withdrawal, applicants have already also identified the various elected species claims in group II.

Respectfully submitted,



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